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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,804	07/28/2003	Arlene R. Howe	MONS:129USC1	4557

46795 7590 03/23/2007

FULBRIGHT & JAWORSKI, LLP
600 CONGRESS AVENUE, SUITE 2400
AUSTIN, TX 78745

EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/628,804	HOWE ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,8-10,13-18,21-23,25-27,30-33,38 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6, 8-10, 13-18, 21-23, 25-27, 30-33 and 38-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 December 2006 has been entered.

2. Claims 1, 4-6, 8-10, 13-18, 21-23, 25-27, 30-33 and 38-39 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The objection to claim 1 because of a misspelling is withdrawn in light of Applicant's amendment of the claim.

Claim Rejections - 35 USC § 112

5. Claims 1, 4-6, 8-10, 13-18, 21-23, 35-27, 30-33 and 38-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of an NPTII selectable marker gene in a plant using kanamycin and paromomycin and certain organosilicone concentrations, does not reasonably provide enablement for a method of detecting the presence of a selectable marker gene in a plant using all the listed selective agents and organosilicone concentrations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last Office action. The rejection is repeated for the reasons of record as set forth in the

Office action mailed 23 June 2006. Applicant's arguments filed 26 December 2006 have been fully considered but they are not persuasive.

The claims are drawn very broadly to a method of detecting the presence of a selectable marker gene product conferring resistance to kanamycin, paromycin, ribostamycin, butirosin, geneticin, or combinations thereof, in any plant by applying or contacting a plant of any species and of any age with any amount of any selective agent and any organosilicone surfactant and assessing the resulting appearance of the plant. Some of the claims specify a particular surfactant, surfactant concentration, selectable marker gene, or plant type or species, but no claims are limited to all these features, so that, for example, the claims that specify a particular surfactant at a particular concentration, call for the use of the method in any plant with any selectable marker gene/selectable agent combination. The specification lacks guidance for carrying out the method of detecting a selectable marker gene, particularly one other than the NPTII gene.

The direct application of a selectable marker and a surfactant to plants is unpredictable. The instant specification indicates that use of the organosilicone SILWET L-77 at concentrations above 0.1% resulted in obvious yellowing of the leaves of nontransgenic corn seedlings of an unspecified age (page 13, lines 5-6). All the further examples use SILWET L-77 concentrations in the range of 0.01%-0.06%, so the effect of the yellowing caused by the higher SILWET L-77 concentrations on the ability to score treated plants for necrosis and/or bleaching caused by the presence of a selective agent was not determined. Severe yellowing would likely interfere with the ability to score the plants, and the specification gives no guidance on how to score treated plants when high SILWET L-77 concentrations are used.

The behavior of different organosilicone surfactants is unpredictable. The bulk of the examples are done using a single organosilicone surfactant, SILWET L-77, but example 9 (pg 18-19 of the specification) shows the results when kanamycin/paromomycin mixture was applied to nontransformed corn seedlings using different SILWET surfactants. In the tests with one of the surfactants, SILWET L-7002, one plant out of six tested showed no visible bleaching. This suggests that not all organosilicone surfactants would behave as SILWET L77 does, and that false positives would be seen when some organosilicone surfactants are used.

These claims encompass all or many herbicide and antibiotic selectable agents and corresponding resistance genes. However, not all antibiotics to which even a single resistance gene confers resistance would respond in the same manner. The instant specification indicates that while the NPTII gene product confers resistance to a number of antibiotics including genenticin and kanamycin, genenticin did not give a clearly defined bleaching and/or necrosis response on nontransgenic corn seedlings, while kanamycin, at least at some concentrations, did (pg 13 of the specification, example 2). Additionally, paromomycin, when used with SILWET L-77 as the only antibiotic on nontransformed corn plants produced a number of plants with no symptoms, *i.e.*, it generated false positives (table on pg 16 of the specification). If three antibiotics that correspond to a single resistance gene behave unpredictably, it is reasonable to expect that antibiotics or herbicides that correspond to other resistance genes would also behave in an unpredictable manner, and that guidance for their use would be required.

The amount of antibiotic and organosilicone needed as a function of the age of the plants is unpredictable. Example 4 of the specification (pg 15) indicates that corn seedlings of different ages needed very different amounts of antibiotic to produce visible necrosis or bleaching. For 1-

week-old corn seedlings, 0.01 mg of antibiotic produced "very dramatic bleaching and necrosis' (lines 11-12), while for corn seedlings two weeks older, 2 to 2.5 times that amount of antibiotic produced only "some bleaching and necrosis" on the leaves (lines 18-20). Plants, corn or otherwise, older than that were not tested, and as the amount of bleaching and necrosis decreased with age of the plant, even when increased amounts of antibiotic were used, guidance would be needed for the application of the method to corn plants older than 3 weeks, soybeans other than 17 days old, and to other plants of any age.

Some markers that work in selection of transformed dicots do not work in selection of monocots. Dekeyser et al (1989, Plant Physiol. 90:217-223) teach that selection of untransformed rice calli by certain selective agents, including kanamycin, is very concentration dependent (pg 221-222, including figure 6). Hauptmann et al (1988, Plant Physiol. 86:602-606) teach that selection of NPTII transformants of *Lolium multiflorum* only works with G418 (geneticin) (pg 602, 1st full paragraph), which as discussed above, did not work in this assay.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate this method for detecting the presence of selectable marker gene products in any plant. There is no claim enabled for all the features noted above.

Applicant urges that the claims are not drawn to detection of any selectable marker, but to ones that correspond to specific selection agents (response pg 6).

This is portion of the rejection is withdrawn.

Applicant urges that one of skill in the art could use the extensive guidance in the specification to determine appropriate experimental conditions with respect the claimed parameters (response pg 6-7).

This is not found persuasive because the guidance in the specification shows that specific claimed embodiments do not work (e.g., paromomycin, concentrations of SILWET L-77 of 0.1%), and that guidance does not teach how to make those work.

Applicant urges that in Example 1, where concentrations of SILWET above 0.1% lead to yellowing, no selective agent was even present; Example 1 was only a preliminary experiment (response pg 7).

This is not found persuasive. Applicant has not shown in the specification or by Declaration that concentrations of SILWET L-77 of 0.1% and above could be used in the claimed method. One can only conclude that that they do not.

Applicant urges that Example 10 shows a condition in which 100% of the transgenic plants were identified; one would understand that the precise levels required would be dependent upon the species, plant age or growth conditions, etc, but determining the correct levels would require only routine experimentation (response pg 7-8).

This is not found persuasive because for certain claimed embodiments, Applicant was only able o show they did not work, thus casting doubt on the enablement of the full scope of claimed embodiments, including those not exemplified at all.

Applicant urges that Example 9 shows that other organosilicone surfactants produced the same results as SILWET L-77; only one in 42 plants showed a false positive - other surfactants are highly predictable (response pg 8).

This is not found persuasive because a 17% false positive rate with L-7002 is not predictable.

Applicant urges that the cited references do not represent the art at the time of filing - numerous selective agents are known for plant transformation (response pg 8-9).

This is portion of the rejection is withdrawn.

Applicant urges that as geneticin did not confer phytotoxic symptoms on the tested plants, no conclusion can be drawn about its use with organosilcone surfactants, but because geneticin is a well-known selective agent in plant transformation getting it to work would not require undue experimentation (response pg 9-10).

This is not found persuasive because 0.03% L-77 was present in Example 2 (see pg 13, line 14). Thus, a conclusion can be drawn about its use with organosilcone surfactants; it is a teaching against what is being claimed. Further, there is no evidence that ribostamycin or butirosin would work.

Applicant urges that the specification indicates that paromomycin was highly effective; the claims relate to a method of using an organosilicine surfactant to enhance the ability to detect the presence of a selectable marker in a plant - inoperative embodiments are permitted (response pg 10).

This is not found persuasive. There was a 30% false positive rate with paromomycin in the presence of L-77. Applicant has not shown in the specification or by Declaration any conditions in which paromomycin works reliably alone. Specifically claimed inoperative embodiments are not permitted.

Applicant urges that experimentation to determine the useful conditions regarding plant age, and the amount of surfactant and antibiotic would be routine, as it was in examples 1-11 (response pg 10-11).

This is not found persuasive because examples 1-11 show that certain claimed embodiments did not work, and provided no evidence that making them work would be routine or even possible.

Applicant urges that not all markers that work for dicots work for monocots, and determining which would work and determining that is not within the scope of the claims (response pg 11).

This is portion of the rejection is withdrawn.

Applicant urges that the usefulness of geneticin for Lolium shows undue experimentation would not be required to identify appropriate conditions for practicing the invention (response pg 11-12).

This is not found persuasive because Applicant could not show that geneticin would work under any conditions.

Double Patenting

6. Claims 1, 4-6, 8-10, 13-18, 21-23, 35-27, 30-33 and 38-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-12 and 14-27 of U.S. Patent No. 6,600,088. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined

claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). The rejection is repeated for the reasons of record as set forth in the Office action mailed 23 June 2006. Applicant's arguments filed 26 December 2006 have been fully considered but they are not persuasive.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The method of detecting the presence of the selectable marker gene product NPTII protein, as claimed in the issued patent, is a species of the genus of methods of detecting the presence of the selectable marker gene product as claimed in the issued patent.

Applicant urges that because it has been acknowledged that they will file a terminal disclaimer upon indication that the claims are otherwise allowable, the rejection should be removed (response pg 12).

This is not found persuasive because the rejection cannot be withdrawn until the terminal disclaimer is actually filed. It is acknowledged that Applicant will file a terminal disclaimer upon indication that the claims are otherwise allowable.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
March 16, 2007

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER